k031805 1/2

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SEP - 9 2003

510(k) SUMMARY

Applicant & Submitter:	DUSA Pharmaceuticals, Inc.
Address:	25 Upton Drive Wilmington, MA 01887
Phone:	978-657-7500
FAX:	978-657-9193
Contact Person:	Scott Lundahl
Preparation Date:	June 9, 2003
Device Submitted:	BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170
Proprietary Name:	BLU-U®
Common Name:	Blue Light Therapy Device
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product Code GEX
Predicate Device:	ClearLight™ Phototherapy Device, Model CL-420
Device Description:	The BLU-U® 4170 is a compact light source that delivers a uniform distribution of blue light to the body with a spectral output at a peak wavelength of 417 nm and a Full Width at Half Maximum (FWHM) of 30 nm (407 – 437 nm). The principal parts of the system include the light unit and floor stand with timer.
Intended Use:	The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170 is intended to provide phototherapeutic light to the body. The BLU-U® 4170 is generally indicated to treat dermatological indications. The BLU-U® 4170 is specifically indicated to treat moderate inflammatory acne vulgaris.

Performance Data:	No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). The BLU-U has the same spectral output, mode of operation, treatment area, and general operating principals as well as the same intended use, the same general and specific indications for use as the predicate device. A data base search has been performed to evaluate any adverse effects of the device that is currently marketed. No data submitted for section 807.92 6[(b)(1)(2)(3c)]
Substantial Equivalence:	The Model 4170 BLU-U® Photodynamic Therapy Illuminator is substantially equivalent to the previously cleared ClearLight™ Phototherapy Device, Model CL 420. The BLU-U has the same intended use and has the same general and specific indications for use as the Clearlight™. The spectral output, mode of operation, treatment area, and general operating principals for the BLU-U® are similar to or the same as the Clearlight™. The BLU-U® and the ClearLight™ are both light devices that are used to treat dermatological conditions by exposing the surface of the skin to light at precise wavelengths. Although there are some differences in method by which each device produces light, these differences do not raise new question of safety or efficacy. Thus, the BLU-U® is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Mr. Scott Lundahl
Director of Regulatory Affairs (Acting)
DUSA Pharmaceuticals, Inc.
25 Upton Drive
Wilmington, Massachusetts 01887

Re: K031805
Trade/Device Name: BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 9, 2003
Received: June 11, 2003

Dear Mr. Lundahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K031805
(if known)

Device Name: BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

Indications for Use: The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170 is intended to provide phototherapeutic light to the body. The BLU-U® is generally indicated to treat dermatological indications. The BLU-U® is specifically indicated to treat moderate inflammatory acne vulgaris.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE OF ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The- Counter Use ____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031805